Attachment 8- 510(k) Summary

OCT 27 2006

510(k) SUMMARY

a. Submitter's Name and Address

TOGO MEDIKIT CO., LTD.
17148-6 Oaza-Hichiya Aza-Kamekawa
Hyuga-Shi, Miyazaki-Ken, Japan 883-0062

b. Contact

Kozo Nagayama Director, Product Quality Center

c. Date prepared

August 4, 2005

d. Name of device

Trade Name: SUPERCATH V
Common Name: Fistula Needle
Classification Name: Blood access device and accessories

e. Predicate devices

This device is substantially equivalent to "PROTECTIV PLUS Safety IV Catheter" (K030571), Togo Medikit's Supercath A.V. Fistula (K854773) and Supercath Z3V (K050114).

f. Device description

The SUPERCATH V fistula catheter is part of any hemodialysis system that connects the patient to the machine and provides access to the patient's blood.

This device is designed for single use and the catheter hub has a built-in hemostatic valve, which assists compression hemostasis when the metallic introducer needle is withdrawn following blood vessel puncture. The metallic introducer needle is retracted into the extendable needle casing to prevent needlestick injury.

g. Substantial equivalence

The SUPERCATH V is substantially equivalent to the PROTECTIV PLUS Safety IV Catheter (K030571) and Togo Medikit's Supercath A.V. Fistula (K854773) and Supercath Z3V (K050114). See Comparison Table 1 below.

Table 1.

Factor	Supercath V	PROTECTIV PLUS	Supercath A.V. Fistula	Supercath Z3V
Same Intended Use	Yes	No	Yes	No
Needlestick Injury Prevention Feature	Yes	Yes	No	Yes
Hemostatic Valve	Yes	No	No	Yes
EtO Sterilized	Yes	Yes	Yes	Yes
Single Sterile Wrapped	Yes	Yes	Yes	Yes
Multiple gauge Sizes and Needle Lengths	Yes	Yes	Yes	Yes

h. Conclusion

The SUPERCATH V has the same intended use as Togo Medikit's Supercath A.V. Fistula (K854773) and similar technological characteristics as the PROTECTIV PLUS Safety IV Catheter (K030571) and the Supercath Z3V (K050114). Similar component materials are used as in prior Supercath models cleared by FDA. Therefore we affirm that the SUPERCATH V is substantially equivalent to the predicate devices listed herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 27 2006

Fumiaki Kanai, Ph.D.
President and CEO
MIC International
4-2-1 Yushima
Bunkyou-ku,
Tokyo 113-0034
JAPAN

Re: K052267
Trade/Device Name: Supercath V
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: August 25, 2006
Received: August 28, 2006

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) NUMBER (If known): K052267

Device Name: Supercath V

Indications for Use:

The Supercath V fistula catheter is intended to access a vein or artery while connected to a blood circuit during kidney dialysis. The Supercath V is intended to minimize inadvertent needlesticks or is intended to reduce accidental needlesticks.

(Please do not write below this line – Continue on other page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ ***OR*** ***Over-the Counter Use*** _____

(Per 21 CFR 801.109)

David G. Segmm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052267